UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEB INVESTMENT MANAGEMENT AB, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ENDO INTERNATIONAL PLC; ENDO HEALTH SOLUTIONS INC.; PAUL V. CAMPANELLI; BLAINE T. DAVIS; MATTHEW W. DAVIS; RAJIV KANISHKA LIYANAARCHCHIE DE SILVA; IVAN GERGEL; SUSAN HALL; DAVID P. HOLVECK; ALAN G. LEVIN; JULIE H. MCHUGH; SUKETU P. UPADHYAY; DANIEL A. RUDIO; ROGER H. KIMMEL; SHANE M. COOKE; JOHN J. DELUCCA; ARTHUR J. HIGGINS; NANCY J. HUTSON; MICHAEL HYATT; WILLIAM P. MONTAGUE; JILL D. SMITH; and WILLIAM F. SPENGLER, Defendants.	Civ. A. No. 2:17-CV-3711-TJS ELECTRONICALLY FILED

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

SEB Investment Management AB ("Plaintiff"), individually and on behalf of the Class,[1] hereby submits this Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint (ECF No. 37) (the "Motion" or "MTD").

I. INTRODUCTION

This case is about Defendants' campaign of misinformation concerning the safety and abuse-deterrent properties of Reformulated Opana ER on numerous investor conference calls and in SEC filings. Their fraud artificially inflated Endo's stock price and caused significant economic losses to Plaintiff and the Class when the truth was revealed. Endo's investors are not the only victims of Defendants' fraud—there is a nationwide epidemic of opioid abuse that Defendants' illicit and deceptive marketing of Reformulated Opana ER has fueled. Government entities across the nation have also commenced litigation to hold Endo accountable and, most recently, the U.S. Department of Justice commenced a criminal investigation into Endo's deceptive marketing practices.

Seeking to extend its monopoly over an extended release formulation of its principal opioid drug, Opana ER, Endo developed Reformulated Opana ER, which it touted as "crush-resistant" and "abuse-deterrent." During the Class Period, Endo told its investors that it was gathering clinical information that supported its application to the FDA for an "abuse-deterrent" label for its new formulation. In truth, the data showed that the reformulated product was not effective at deterring abuse, but instead was responsible for an alarming increase in IV abuse rates of the drug and other associated side effects. These and numerous materially false or misleading statements concerning the safety and abuse-deterrent qualities of Reformulated Opana ER are at issue in this

[1] Unless otherwise defined herein: (i) capitalized terms have the meanings ascribed to them in Plaintiff's Amended Complaint for Violations of the Federal Securities Laws (ECF No. 36) (the "Complaint"); (ii) references to "¶ __" are to paragraphs in the Complaint; (iii) internal quotation marks and citations are omitted; and (iv) emphasis is added.

case. For example, in their statements promoting the putative abuse-deterrent properties of Reformulated Opana ER, Defendants concealed existing, available data demonstrating that, *inter alia*: (i) there was an ***increased*** rate of abuse of Reformulated Opana ER through ***injection***; and (ii) such IV abuse was associated with thrombotic microangiopathy ("TMA") and thrombotic thrombocytopenic purpura ("TTP"), potentially fatal coagulation disorders unique among opioids to Reformulated Opana ER. Although Defendants concealed these serious and heightened risks of Reformulated Opana ER from investors, these very same risks caused the FDA to demand on June 8, 2017, that Endo voluntarily withdraw the drug from the market.

Defendants' bid for dismissal of the Complaint ignores numerous critical facts at the core of Plaintiff's claims. Most egregiously, Defendants baselessly contend that this case alleges "fraud by hindsight," while mischaracterizing and otherwise failing to address Plaintiff's allegations pertaining to Defendants' *contemporaneous* knowledge and concealment of the increased IV abuse of Reformulated Opana ER and the unique and potentially fatal risks that the drug presented—facts set forth in the very same data that Defendants referenced in their misleading public statements celebrating the putative effectiveness of Reformulated Opana ER's abuse-deterrent properties. Defendants likewise seek to dodge the Complaint's allegations addressing their statements that misleadingly compared Reformulated Opana ER's ability to deter abuse with the abuse-deterrence effectiveness of reformulated OxyContin.[2] Defendants' inability or unwillingness to confront critical aspects of the Complaint dooms their Motion. When viewed in its entirety (rather than through the self-serving lens of Defendants' Motion), the Complaint sufficiently pleads each of Plaintiff's claims.

[2] Original Opana ER, like other opioids, such as OxyContin (extended release oxycodone), was highly-addictive and commonly abused through chewing, grinding, snorting, and intravenous ("IV") injection. In 2010, the FDA approved an abuse-deterrent formulation of OxyContin that contained properties that effectively lowered the rate of all methods of abuse of that product, including IV injection. ¶ 89.

First, the Complaint alleges in detail that Defendants touted data that showed lower intranasal abuse rates of Reformulated Opana ER, while concealing the data in the very same studies that showed a dramatic and life-threatening migration of abuse to intravenous injection, accompanied by heightened and unique risks, including potentially fatal TMA/TTP. Defendants' intentional omission of this adverse data was particularly egregious given that the FDA, in denying Endo's original application for an abuse-deterrent label in May 2013, indicated that the potential for increased IV abuse was a "troubling" concern. By obscuring and concealing this adverse data, the Defendants made materially false or misleading statements during the Class Period concerning, *inter alia*, Reformulated Opana ER's: (i) putative safety and abuse-deterrent qualities; (ii) purported similarities to reformulated OxyContin and thus the likelihood of Endo achieving an abuse-deterrent label like OxyContin; and (iii) the sufficiency and nature of the data Endo was amassing in support of its application for an abuse-deterrent label. As set forth below in Sections IV.A.5 and IV.B, Defendants' misstatements alleged in the Complaint were not forward-looking statements protected by adequate cautionary language, inactionable opinions, or immaterial "puffery." Instead, Plaintiff sufficiently alleges that each challenged statement was materially false or misleading when made. *See* Section IV.A.1-4.

Second, the Complaint's collective allegations raise the required strong inference of scienter. *See infra* Section IV.C. Each of the Individual 10(b) Defendants (defined below) spoke specifically on investor conference calls, or made statements in SEC filings, about Reformulated Opana ER's safety and abuse-deterrent attributes, including what they contended the data they were gathering revealed. This very same data, with which Defendants were clearly familiar, actually showed elevated rates of abuse of Reformulated Opana ER. Thus, Defendants either knowingly concealed these adverse facts or were reckless in disregarding the danger that their

statements were materially misleading absent disclosure of these facts. Defendants' conduct raises a strong inference of scienter that is more cogent and compelling than Defendants' suggestion that Endo and Reformulated Opana ER were merely hapless victims of "a new focus on opioid abuse." MTD at 3, 30.

Defendants' other arguments for dismissal likewise fail. As set forth below in Section IV.E, Plaintiff's claims under the Securities Act differ materially from those alleged in *Public Employees' Retirement System of Mississippi v. Endo International, plc*, No. 2017-02081-MJ (Chester C.C.P.) ("*MissPERS*"), and preclude applying the *Colorado River* doctrine's "extraordinary and narrow exception" to this Court's jurisdiction. Moreover, the Complaint bears no resemblance to a "puzzle pleading." Instead, courts routinely sustain complaints alleging federal securities law claims that include internal cross-references designed to limit the length of the pleading, like Plaintiff's Complaint here. *See infra* Section IV.F.

For the reasons noted above and discussed more fully below, the Motion should be denied.

II. STATEMENT OF FACTS

A. Opana ER's Importance to Endo

Launched in 2006, original Opana ER soon became one of Endo's highest grossing products, earning ***hundreds of millions of dollars*** annually. ¶¶ 4, 56, 307. By 2010, original Opana ER was Endo's second largest revenue generator, earning nearly $240 million (or 14%) of its total revenues that year. ¶ 56. Eying the lucrative revenues to be gained, Impax Laboratories, Inc. ("Impax") and other drug manufacturers soon began seeking FDA approval for their own generic versions of extended-release oxymorphone hydrochloride to compete directly with original Opana ER. ¶ 60. In response, Endo hatched a plan to stave off generic competition and maintain market exclusivity for the drug by developing a new formulation of Opana ER that would effectively extend the life of its patents—namely, one capable of deterring abuse commonly

associated with the original formulation (i.e., chewing, crushing, or grinding and snorting the drug, or by manipulating it for injection). ¶ 66.

To this end, Endo aggressively defended its original Opana ER patents in court, including by making significant payments to settle these lawsuits on terms that delayed generic versions of original Opana ER from coming to market—which the FTC dubbed improper "pay-for-delay" settlements. ¶¶ 64-65.[3] In 2010, the FDA approved an abuse-deterrent formulation of OxyContin, for which it subsequently approved an abuse-deterrent label, making the success of Reformulated Opana ER all the more critical.

B. The FDA Denies Abuse-Deterrent Labeling for Reformulated Opana ER

Endo filed a new drug application ("NDA") for Reformulated Opana ER on July 7, 2010, heralding the formulation as crush-resistant and abuse-deterrent, and sought FDA approval for abuse-deterrent labeling. ¶¶ 66-73. The FDA approved the NDA on December 9, 2011, but denied Endo's request for abuse-deterrent labeling, concluding that the available data provided inadequate support. ¶ 78.

Although the FDA refused to label Reformulated Opana ER as abuse-deterrent, Endo persisted in its efforts to preserve market exclusivity and profits for its Opana ER franchise. ¶¶ 81-82. When it began marketing Reformulated Opana ER in February 2012, Endo started phasing out the original formulation, and notified the FDA on May 31, 2012, that it discontinued original Opana ER for "***safety reasons***." *See, e.g.*, ¶¶ 11-12, 83. On August 10, 2012, Endo filed a Citizen Petition with the FDA formally asking it to determine that Endo withdrew original Opana ER for safety reasons. ¶ 84. In support, the Company claimed that Reformulated Opana ER offered safety

[3] As a result of Endo's settlement with Impax, the first manufacturer to gain approval of generic Opana ER, Impax agreed to delay its market entry until January 1, 2013, precluding all other generic filers from entering the market for 180 days following Impax's launch. ¶ 61.

advantages over the original formulation in terms of its ability to deter abuse, and that the FDA should therefore suspend or withdraw all applications for generic versions of original Opana ER. ¶¶ 84-85. If Endo had prevailed on its Citizen Petition before year-end (given Impax's pending generic oxymorphone hydrochloride launch on January 1, 2013), the Company would have successfully fended off generic competition. ¶ 13.

C. Endo Misrepresents Reformulated Opana ER's Safety and Sustainability, While Concealing Data Demonstrating Serious Safety Concerns

The Class Period begins on November 30, 2012, when Endo took the dramatic step of suing the FDA for its alleged failure to timely decide Endo's Citizen Petition. ¶ 93. In a press release announcing the lawsuit, Endo stated that post-marketing data submitted with its Citizen Petition "***show [a] dramatic decrease in abuse rates of reformulated OPANA® ER designed to be crush-resistant when compared to non-tamper resistant formulation***." ¶¶ 157, 159. In response, the FDA stated, "***Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health***" and that the Citizen Petition was "***a thinly-veiled attempt to maintain its market-share and block generic competition***." ¶ 93. The court dismissed Endo's suit, and Impax began selling its generic version of original Opana ER in 2013. ¶ 94.

The next month, Endo filed a supplemental new drug application ("sNDA") with the FDA, again seeking abuse-deterrent labeling for Reformulated Opana ER. ¶ 95. Defendants also continued to tout the safety benefits of the drug, including its purportedly "crush-resistant" properties and purportedly lower "abuse rates" seen in post-marketing data, and claimed that "sufficient evidence exists to support a determination by FDA that the old formulation of Opana ER was discontinued for reasons of safety, which serves the public health." ¶¶ 161-66, 168, 170-83, 190-94, 198. On April 23, 2013, after the FDA granted a Citizen Petition determining that the original formulation of OxyContin was withdrawn for safety reasons in favor of its abuse-deterrent

formulation, Endo doubled-down, falsely claiming that Reformulated Opana ER was "virtually identical" to reformulated OxyContin, and that Endo's Citizen Petition therefore should also be granted. ¶¶ 105-07, 185-87, 195, 198.

On May 10, 2013, the FDA denied both Endo's Citizen Petition and its renewed request for abuse-deterrent labeling, finding that Reformulated Opana ER "can be readily prepared for injection" and that original Opana ER was not withdrawn for safety reasons. ¶¶ 107-09. The FDA further: (i) stated that the post-marketing data Endo submitted with its request for abuse-deterrent labeling was "inconclusive" and "suggests the troubling possibility that ***a higher (and rising) percentage of [reformulated Opana ER] abuse is occurring via injection*** than was the case with [original Opana ER]" (¶ 111); and (ii) rejected Endo's claims that Reformulated Opana ER was "virtually identical" to reformulated OxyContin (¶¶ 108, 112).

D. While Continuing to Conceal Data Demonstrating Serious Safety Concerns, Endo Reassures Investors That Reformulated Opana ER is Safe and Viable

With the inception of generic competition, Endo focused on trying to maintain the lucrative revenue stream from Reformulated Opana ER. Central to these efforts were Defendants' continued representations that Reformulated Opana ER was "crush-resistant," that available data showed it was effectively deterring abuse, and that Endo was working to obtain additional supporting data. *See* ¶¶ 200-62. Contrary to Defendants' statements: (i) Reformulated Opana ER was susceptible to abuse by grinding and snorting, chewing, and injection (¶¶ 67-69, 71-73); (ii) the properties that supposedly made the drug safer actually drove *increased levels of IV abuse* (¶¶ 18, 88, 92, 98-99, 102, 109-112, 122-27, 130-31); and (iii) IV abuse of the drug caused numerous incidents of TMA/TTP (¶¶ 86, 111, 130-31).

Immediately following the FDA's rejection of Endo's Citizen Petition, non-public data sources that Endo sponsored, had access to, and regularly received and analyzed (i.e., NAVIPPRO,

RADARS),[4] confirmed a shift in the predominant form of abuse of Reformulated Opana ER from intranasal to IV injection and that IV abuse had escalated. ¶¶ 123-26. Nevertheless, Defendants claimed that this data demonstrated declines in "abuse rates" for the drug and thus improved Endo's prospects of obtaining an abuse-deterrent label (*see, e.g.*, ¶¶ 88, 123-28, Ex. A, § 1). These misrepresentations were included in the $2.3 billion June 2015 Offering (¶¶ 369-71). Defendants, however, failed to disclose the marked increase in Reformulated Opana ER IV abuse. ¶¶ 370-73.

E. The Truth about Reformulated Opana ER's Safety and Prospects Emerges

The truth about Reformulated Opana ER's actual safety profile and risks gradually emerged during the Class Period. On January 10, 2017, the FDA announced that it was convening an Advisory Committee on March 13-14, 2017, to review post-marketing abuse data for Reformulated Opana ER and the risk/benefit profile of the drug (¶ 137), the very same data that Endo had been gathering and had produced to the FDA a year earlier (¶ 133). On March 9, 2017, the FDA disseminated a briefing document in advance of the Advisory Committee, which reflected the FDA's concern that Endo's post-marketing abuse data was "compelling" evidence of the ***lack of safety*** of the drug because "***the reformulation caused a shift in non-oral routes [of abuse] from predominately nasal to predominately injection***." ¶ 141. The FDA further noted the number of reports of TMA/TPP from IV abuse of Reformulated Opana ER. *Id.* On March 14, 2017, the Advisory Committee voted 18-8 that the risks associated with Reformulated Opana ER outweighed its benefits. ¶ 146. On June 8, 2017, the FDA demanded Endo withdraw Reformulated Opana ER from the market in light of the serious health risks it presented. ¶ 149.

[4] The National Addictions Vigilance Intervention and Prevention Program ("NAVIPPRO"), is a national program that Endo helped found in 2005 to perform surveillance of substance abuse. ¶ 88. The Researched Abuse Diversion and Addiction-Related Surveillance System ("RADARS") provides surveillance data to meet the needs of pharmaceutical companies, policy makers and others in addressing the concerns of prescription drug abuse. *Id.*

III. LEGAL STANDARD

A complaint may not be dismissed for failure to state a claim if it "contain[s] sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Curran v. Freshpet, Inc.*, 2018 WL 394878, at *3 (D.N.J. Jan. 19, 2018) (on motion to dismiss, court must accept as true all facts alleged and draw all reasonable inferences in plaintiff's favor); *OpenGate Cap. Grp. LLC v. Thermo Fisher Sci. Inc.*, 2014 WL 3367675, at *5 (D. Del. July 8, 2014) ("The purpose of a Rule 12(b)(6) motion to dismiss is to test the sufficiency of a complaint, not resolve disputed facts or decide the merits of the case.").

A claim is facially plausible when the facts pled allow the court reasonably to infer that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 678. Securities fraud claims must also satisfy the pleading requirements of Federal Rule of Civil Procedure ("Rule") 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b). *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 466-67 (E.D. Pa. 2014).[5]

IV. ARGUMENT

The Complaint alleges plausible claims under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, and satisfies the particularity requirements of Rule 9(b) and the PSLRA. The Complaint also alleges plausible claims under Sections 11 and 15 of the Securities Act, 15 U.S.C. §§ 77k and 77o. Defendants concede Plaintiff has adequately pled all but two elements of its claims: (i) falsity; and (ii)

[5] Although Plaintiff's Section 11 claim is subject to the notice pleading standard of Rule 8(a), the Complaint's allegations underlying Plaintiff's Securities Act claims also satisfy Rule 9(b) for the reasons set forth with respect to Plaintiff's Section 10(b) claims. *See infra* Section IV.A.

scienter.[6] Defendants' challenges to Plaintiff's falsity and scienter allegations are meritless, and Defendants' Motion should be denied in its entirety.

A. Plaintiff Adequately Pleads Material Misrepresentations and Omissions

To adequately plead a false or misleading statement, Plaintiff must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . state with particularity all facts on which that belief is formed." *Viropharma*, 21 F. Supp. 3d at 467; *see also W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, 2015 WL 3755218, at *9 (E.D. Pa. June 16, 2015) (noting "nearly identical" particularity requirements of Rule 9(b) and the PSLRA).

"[A] statement is false or misleading if it is factually inaccurate or additional information is required to clarify it." *In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 543 (D.N.J. 2002); *See also In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 453 (S.D.N.Y. 2005) (a statement is misleading if it would give a reasonable investor the "impression of a state of affairs that differ[s] in a material way from the one that actually exist[s]"); *In re Cephalon Sec. Litig.*, 1997 WL 570918, at *2 (E.D. Pa. Aug. 29, 1997) (falsity exists if contemporaneous facts are inconsistent with defendant's public statements). Moreover, a statement that is literally true, can nonetheless be materially misleading by omission. *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011) ("The law is well settled [] that so-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud."), *rev'd on other grounds*, 568 U.S. 442 (2013). Accordingly, "[t]here is a duty to disclose information when disclosure is

[6] The elements of Plaintiff's Section 10(b) and SEC Rule 10b-5 claims are: (i) a material misrepresentation or omission; (ii) scienter; (iii) in connection with the purchase or sale of a security; (iv) reliance; (v) economic loss; and (vi) loss causation. *Viropharma*, 21 F. Supp. 3d at 466 (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)). To state a Section 11 claim, Plaintiff "must allege that [it] purchased securities pursuant to a materially false or misleading registration statement." *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 273 (3d Cir. 2004).

necessary to make defendants' other statements, whether mandatory or volunteered, not misleading." *In re Aetna, Inc. Sec. Litig.,* 34 F. Supp. 2d 935, 948 (E.D. Pa. 1999); s*ee also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (disclosure duty arises where fact is necessary to make statements made not misleading).

The Complaint readily satisfies these standards because it identifies: (i) statements Defendants made during the Class Period concerning Reformulated Opana ER that were affirmatively false, gave a misleading impression, or omitted material facts necessary to render the statements made not misleading; (ii) the date and author/speaker of each statement; (iii) why each statement was false or misleading at the time it was made; and (iv) detailed facts supporting these allegations, including the contemporaneous data from Endo's pre-approval and post-marketing studies that contradicted Defendants' public statements or rendered them misleading.

1. Defendants' Misrepresentations of the Data Supporting Reformulated Opana ER's Purported Abuse-Deterrent Qualities Are Actionable

Plaintiff alleges actionable misrepresentations based on Defendants' statements concerning: (i) Reformulated Opana ER's purported "abuse-deterrent" properties (¶¶ 170-72, 186, 198), including its "crush-resistant" features (¶¶ 174, 176-77, 179, 181, 186, 190, 194, 200, 202-03, 208, 213, 215, 217, 221, 223, 229, 235, 239, 244, 248, 252);[7] and (ii) declines in "abuse rates" supposedly observed in post-market surveillance of the drug (¶¶ 157, 159, 161, 170, 173, 182-83, 186, 190, 198, 200).[8] *See also* Ex. A § 1. Plaintiff also alleges an actionable false statement based

[7] Defendants also repeatedly touted Reformulated Opana ER as "designed to be crush-resistant" (¶¶ 157, 159, 161, 168, 174, 176, 190, 194, 202-03, 208, 213, 215, 217, 221, 223, 229, 235, 239, 244, 248, 252), and compared it to the "non-crush-resistant" or "non-tamper resistant formulation of Opana ER" (¶¶ 157, 159, 161, 168). The statements touting Reformulated Opana ER as "crush-resistant" and "designed to be crush-resistant" set forth in Endo's 2014 Form 10-K and 1Q15 Form 10-Q were also incorporated into the June 2015 Offering materials. ¶ 371.

[8] *See, e.g.*, ¶¶ 157, 159 (claiming post-marketing surveillance data "show [a] dramatic decrease in abuse rates of reformulated OPANA® ER designed to be crush-resistant when compared to non-tamper resistant formulation" and "[c]urrent data monitoring abuse rates show a substantial decrease in abuse since the launch of the reformulated product"); ¶ 161 ("surveillance data collected . . . through the third quarter of 2012 suggest that the introduction of reformulated Opana ER . . . reduced abuse rates of the product"); ¶ 168 ("the introduction in the first quarter of 2012

on Defendants' representation that "available data from post-marketing studies suggest a reduction in *non-oral* abuse for Reformulated Opana ER." ¶ 186.

Contrary to these statements, *contemporaneous* data from Endo's pre-approval studies (Studies 108, 109, 901, and 902) showed that Reformulated Opana ER: (i) was neither "abuse-deterrent," nor "crush-resistant," and could still be cut, ground, chewed, and injected, which compromised the extended release feature of the drug; (ii) could "be prepared for insufflation (snorting) using commonly available tools and methods"; (iii) could more easily be prepared for injection than original Opana ER; and, therefore (iv) provided only "limited" resistance to manipulation for abuse. *See* ¶¶ 67-78, 110. In addition, *the same surveillance data* Defendants touted as showing declines in "abuse rates" actually showed an increased trend in IV abuse rates for the drug by no later than third quarter 2013, which Defendants concealed from investors (¶¶ 87-92, 98-99, 102, 109-112, 122-27). Post-marketing data from the FDA's adverse event reporting system ("FAERS") likewise showed: (i) a shift in the route of abuse from snorting to injection; (ii) increasing rates of IV abuse following the introduction of Reformulated Opana ER; and (iii) numerous deadly incidents of TMA/TPP-like illnesses associated with IV abuse of Reformulated Opana ER. ¶¶ 86, 125, 127, 130-31.

These data also contradicted or rendered materially misleading Defendants' statements that: (i) "sufficient evidence exists to support the determination [requested in Endo's Citizen Petition to the FDA] that the old formulation of Opana ER was discontinued for reasons of safety" (¶¶ 158-59, 163-64, 168, 191-92); and (ii) "surveillance data supports removal of old formulation brand and generics from the market for reasons of safety" (¶¶ 166, 177, 181). Even after the FDA

---

of the reformulated Opana ER . . . is reducing rates of abuse"); ¶ 174 ("the data that we've collected in those two surveillance databases clearly show a significant reduction in abuse"); *see also* ¶¶ 170, 173, 179, 182-83, 186, 190, 198, 200.

rejected Endo's claim that original Opana ER was withdrawn for safety reasons, Defendants continued to falsely tout the purported "abuse-deterrent" attributes of Reformulated Opana ER. *See supra* p. 11 and note 7.

Defendants' failure to disclose the adverse data showing the increase in IV abuse of Reformulated Opana ER was particularly egregious given that the FDA had noted in its denials of Endo's Citizen Petition and sNDA, the "troubling possibility that a higher (and rising) percentage of [Reformulated Opana ER] abuse is occurring via injection than was the case with [original Opana ER]." ¶ 111. Indeed, the FDA noted that Reformulated Opana ER could "be readily prepared for injection." ¶¶ 107, 110. Thus, the FDA made clear to Endo that data regarding IV abuse was material to the FDA's evaluation of the safety of the drug.

Courts readily sustain as actionable representations concerning the safety of a drug or its prospects when such statements are contradicted by *contemporaneous* scientific data, as is the case here. *See, e.g.*, *Viropharma*, 21 F. Supp. 3d at 469 (sustaining claims based on drug manufacturer's statements expressing confidence that drug would receive additional period of exclusivity, despite manufacturer's access to contrary information); *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 2011 WL 3444199, at *10 (D.N.J. Aug. 8, 2011) ("positive statements about [drug's] commercial success in light of its 'exceptional safety profile' were misleading for failure to completely and accurately represent information known to Merck about the drug," including from Merck's own analyses); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *15 (D.N.J. Aug. 28, 2017) (statements that the "totality" and "consistency" of data met requirements for FDA approval were actionable where study failed its primary endpoints); *Frater v. Hemispherx*

Biopharma, Inc., 996 F. Supp. 2d 335, 346-47 (E.D. Pa. 2014) (sustaining claims based on statements about prospects for drug approval).[9]

Indeed, once Defendants chose to speak on these topics—i.e., to characterize Reformulated Opana ER as abuse-deterrent and tout the purported declines in abuse rates observed in post-marketing surveillance data—they were obligated to disclose all material facts on those issues. In particular, these statements triggered a duty to disclose that Reformulated Opana ER was actually susceptible to abuse by chewing, grinding and snorting, and manipulation for injection, and was increasingly abused by injection, as revealed in the same data they touted as showing declines in abuse rates. *See, e.g., In re Providian Fin. Corp. Sec. Litig*., 152 F. Supp. 2d 814, 824-25 (E.D. Pa. 2001) (once defendant puts a topic "in play," it must disclose all information on that topic that would alter the mix of available information (citing *Shapiro v. UJB Fin. Corp*., 964 F.2d 272, 281-82 (3d Cir. 1992) ("By addressing the quality of a [matter], a defendant declares the subject of its representation to be material to the reasonable shareholder, and thus is bound to speak truthfully."))); *Meyer v. Jinkosolar Holdings Co., Ltd*., 761 F.3d 245, 250 (2d Cir. 2014) ("Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth.").

[9] Relying on *California Public Employees' Retirement System v. The Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004) and *Clark v. Comcast Corp.*, 582 F. Supp. 2d 692, 705 (E.D. Pa. 2008), which merely observe that "barebones" allegations fail to satisfy applicable pleading standards, Defendants wrongly contend that Plaintiff has not pled sufficient facts regarding Endo's pre-approval studies to support falsity. MTD at 21. Plaintiff, however, specifically alleges: (i) that Endo conducted these studies prior to its July 2010 NDA for Reformulated Opana ER, which included these studies; (ii) the endpoints these studies assessed, and their respective results; and (iii) the FDA's detailed conclusions regarding the same, as reflected in a December 22, 2010 review. ¶¶ 66-72. Thus, these studies are distinguishable from the vague internal memorandum at issue in *Chubb*. Further, unlike in *Chubb*, Defendants' contemporaneous knowledge of the results of these studies and corresponding FDA conclusions is established through Endo's express reliance upon these same studies in seeking FDA approval of Reformulated Opana ER. *See infra* IV.C (collecting cases). At a minimum, Defendants were reckless in championing Reformulated Opana ER as "crush-resistant" and "abuse-deterrent" based upon data demonstrating the opposite, as the FDA concluded in denying Endo's initial request for abuse-deterrent labeling.

Further, in light of the data from Endo's pre-approval studies and post-marketing surveillance which showed increased levels of IV abuse of Reformulated Opana ER and associated incidents of TMA/TTP, Defendants also had no truthful basis upon which to claim that Endo had "sufficient and robust enough data" to support its Citizen Petition or an abuse-deterrent label. ¶¶ 198, 204, 206. Nevertheless, Defendants positively touted Endo's "active clinical program," "dialogue," "collaboration" and meetings with the FDA regarding the length and robustness of post-marketing data required to support an abuse-deterrent label for Reformulated Opana ER, and "momentum [] generated" surrounding the same, as leading to a "stronger" abuse-deterrent label. ¶¶ 206, 210-11, 219, 225-27, 231-33, 237-38, 241-42, 246, 250. As set forth herein, contrary to these statements, Defendants' knew that post-marketing data showed a persistent and dramatic increase in IV abuse rates for Reformulated Opana ER compared to original Opana ER, and that numerous potentially deadly events associated with IV abuse of the drug put its viability at risk. Courts routinely sustain claims based on such deception. *See, e.g.*, *Viropharma*, 21 F. Supp. 3d at 471 (statements of confidence in the prospect of achieving additional exclusivity period for drug were actionable); *In re Cell Pathways, Inc., Sec. Litig.*, 2000 WL 805221, at *7, *11 (E.D. Pa. June 20, 2000) (statements touting progress of phase III study and anticipated NDA filing and approval held actionable).

2. Defendants' Failure to Disclose the Increased Trends in IV Abuse with Reformulated Opana ER is Actionable

Plaintiff also adequately alleges claims under Section 10(b) of the Exchange Act and Section 11 of the Securities Act based upon Defendants' failure to disclose, under Item 303 of Regulation S-K, 17 C.F.R. § 229.303, the material adverse trends in IV abuse apparent in post-marketing surveillance data by no later than 3Q13. *See* Ex. A § 2. Indeed, Defendants do not dispute that Plaintiff has adequately alleged that the post-marketing data showed an increased

adverse trend in IV abuse with Reformulated Opana ER and the significant risks associated therewith. Such trends gave rise to a disclosure obligation under Item 303. *See Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101-04 (2d Cir. 2015) (failure to comply with Item 303 can give rise to liability under Rule 10b-5 (discussing *Oran v. Stafford*, 226 F.3d 275, 288 (3d Cir. 2000) as in *accord*)); *see also Silverstrand Invs. v. AMAG Pharm., Inc*., 707 F.3d 95, 103-04 (1st Cir. 2013) (sustaining Section 11 claim based on omission under Item 303 of trend in adverse events for drug upon whose commercial success company's profits depended). Defendants' sole argument to the contrary, relegated to a footnote, rests on the same incorrect hindsight argument that Defendants seek to apply to the remainder of Plaintiff's claims (MTD at 19 n.11) which, for the reasons set forth in Section IV.A.4, *infra*, are invalid.

Defendants also do not dispute that Plaintiff adequately alleges actionable omissions under Item 503 of Regulation S-K, 17 C.F.R. § 229.503 in connection with the June 2015 Offering arising from Defendants' failure to disclose the significant risk of regulatory action that the increased trends in IV abuse of the drug and unique health risks related thereto presented. ¶ 373. *See Silverstrand*, 707 F.3d at 103-04 (omission of increase in adverse events for drug upon whose commercial success company's profits depended actionable under Item 503); *In re WorldCom, Inc. Sec. Litig*., 346 F. Supp. 2d 628, 690-92 (S.D.N.Y. 2004) (omission of deteriorated condition of key business actionable under Item 503).

3. Defendants' Statements Comparing Reformulated Opana ER to Reformulated OxyContin Are Actionable

Plaintiff also pleads that Defendants' statements touting purported similarities between Reformulated Opana ER and reformulated OxyContin (for which the FDA approved abuse-deterrent labeling) are actionable. ¶¶ 89, 105-06, 120, 129, 185-87, 195, 198, 219, 237; *see also* Ex. A § 3. Contrary to Defendants' assertions that the two drugs possessed "virtually identical"

abuse-deterrent properties, post-marketing data actually showed they were very different: (i) whereas original OxyContin posed an increased potential for intranasal abuse compared to reformulated OxyContin, Reformulated Opana ER data showed that it could still be prepared for snorting using commonly available tools and methods; and (ii) unlike reformulated OxyContin, which deterred IV abuse by forming a viscous hydrogel that could not pass through a needle, Reformulated Opana ER could be "***readily prepared for injection***." ¶¶ 107-08, 112, 121, 189, 195-96, 198-99, 219-20.

These facts are sufficient to allege false or misleading statements. *See, e.g., In re XenoPort, Inc. Sec. Litig.*, 2011 WL 6153134, at *4 (N.D. Cal. Dec. 12, 2011) (statement that drug had a safety profile "very similar if not identical to" another drug adequately alleged as false because of differences between the drugs); *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 331-32 (S.D.N.Y. 2014) ("omission, combined with the statement that [product] caused side effects 'similar' to those caused by traditional treatment methods, is sufficient to allege that investors were misled about the safety of the Company's product"); *City of Livonia Emps.' Ret. Sys. v. Wyeth*, 2010 WL 3910265, at *2, 5 (S.D.N.Y. Sept. 29, 2010) (statements that drug was "[s]imilar to Effexor XR in terms of efficacy, safety, and tolerability" were actionable).[10]

4. Defendants' Receipt of Contemporaneous Data Contradicting Their Statements Upends Their Fraud-by-Hindsight Challenge

In response to Plaintiff's allegations that Defendants possessed data that contradicted the statements described above at the time such statements were made, Defendants foist a spurious fraud-by-hindsight argument. Fraud-by-hindsight refers to "the implication that [subsequent] bad

[10] Defendants challenge their statements comparing Reformulated Opana ER to reformulated OxyContin only indirectly in the so-called "Statements of Opinion" chart appended to their Motion. MTD, Ex. 4. Defendants, however, do not reference these statements anywhere in in the body of their Motion. For the reasons set forth in Section IV.B.2, *infra*, Defendants' unsupported blanket characterization of these statements as "subjective opinions and interpretations of [] data" fails. MTD at 22.

results mean that statements or actions at the time of the incident must have been untrue or misleading." *In re Heckmann Corp. Sec. Litig*., 869 F. Supp. 2d 519, 538 (D. Del. 2012). "Misstatements of existing fact," like those alleged here, "are not mere fraud by hindsight." *Freudenberg v. E*Trade Fin. Corp*., 712 F. Supp. 2d 171, 192 (S.D.N.Y. 2010).

Here, Plaintiff alleges that data *pre-dating* the Class Period—which Defendants relied upon in connection with Endo's Reformulated Opana ER NDA—showed that the drug could still be manipulated for abuse by chewing, cutting, grinding, and injection. ¶¶ 67-69, 71-73, 160. Further, Plaintiff alleges that Defendants had access to and repeatedly referred to non-public post-marketing data—which they accumulated from the time Reformulated Opana ER entered the market in February 2012 through Endo's submission of this data to the FDA in 2016—in publicly touting the purported abuse-deterrent attributes of the drug. Contrary to Defendants' representations that this data showed a decline in abuse rates of Reformulated Opana ER, the data actually showed that a higher and rising percentage of abuse was occurring by injection with Reformulated Opana ER versus original Opana ER. ¶¶ 87-92, 98-99, 102, 109-12, 123-27, 130-31, 141-44, 203. This data conflicted with Defendants' Class Period representations touting the "abuse-deterrent" and "crush-resistant" properties of Reformulated Opana ER, and undermined their statements boasting purported declines in "abuse rates." This is not fraud-by-hindsight based upon the FDA's June 8, 2017 demand that Endo remove the drug from the market; it is just plain fraud based upon Defendants' deliberate decision to misrepresent and conceal known facts bearing on Reformulated Opana ER's safety profile and viability. *See, e.g.*, *Institutional Inv'rs Grp. v. Avaya, Inc*., 564 F.3d 242, 269 (3d Cir. 2009) (rejecting fraud-by-hindsight argument where shareholders did "not claim merely [the] statements turned out to be wrong, and therefore must have been fraudulent").

Other than their unsupported intimation that Plaintiff merely alleges that Defendants must have known of the risks that Reformulated Opana ER presented based upon the FDA's demand that Endo remove the drug from the market, Defendants' premise their fraud-by-hindsight argument upon their misrepresentation of the dates of post-marketing data summarized in charts set forth in the Complaint. MTD at 19 (incorrectly asserting Plaintiff relies on data from 2016 and 2017, which are actually the years Endo "***submitted***" reports reflecting the underlying data to the FDA, and the FDA "***published***" its conclusions regarding such data). The dates that Endo submitted reports summarizing this data to the FDA, or upon which the FDA published its conclusions regarding the data, do not reflect the dates of the underlying data. Here, such data was reported regularly from the time Reformulated Opana ER entered the market in February 2012, including in NAVIPPRO reports Endo received dated February 22, May 18, August 31, November 2, 2012, and February 5, 2013, and RADARS reports dated October 30, 2012 and February 10, 2013 (¶¶ 88, 99), and Endo continued to receive and rely upon this data during the Class Period. Accordingly, the Complaint satisfies Defendants' contention that "a statement or omission must have been misleading at the time it was made," based on facts that were "known or knowable," not "subsequent events." MTD at 18.

Defendants' reliance upon the non-precedential decision in *In re Amarin Corp., PLC Securities Litigation*, 689 F. App'x 124, 131 (3d Cir. 2017) (MTD at 20) is also misplaced. There, the plaintiff challenged the defendants' statements that a costly, long-term clinical trial was "not required" to be completed before FDA would approve its drug, based on FDA's acceptance of a protocol for short-term studies assessing a surrogate endpoint in lieu thereof, notwithstanding the FDA's express reservation of rights to rescind its acceptance of the surrogate endpoint data after "review." The court concluded therefore that the plaintiff's allegations "reli[ed] on the fact the

FDA ultimately rejected [the short term study data] after a review of "new" scientific data" that did not exist at the time of the alleged misstatements, as opposed to facts contradicting defendants' the statements at the time they were made—and, hence, "amount[ed] to pleading 'fraud by hindsight." *Id*. at 131. Here, in contrast to *Amarin*, the FDA *rejected* Endo's initial request for abuse-deterrent labeling based upon Endo's insufficient data, provided a roadmap to Endo for the outcome study it required (the "insufflation study," a/k/a Studies 113 and 114), and stated that Endo would need sufficiently robust post-marketing data to demonstrate that Reformulated Opana ER actually deterred abuse.

5. The PSLRA Safe Harbor Does Not Apply to Any of Defendants' Misstatements

The PSLRA safe harbor protects only those statements that are forward-looking and accompanied by meaningful cautionary language or where plaintiff fails to establish that defendants had actual knowledge that a forward-looking statement was false. *See* 15 U.S.C. § 78u-5(c). Defendants contend that certain of their alleged misstatements are forward-looking statements protected under the PSLRA safe harbor. *See* MTD, Ex. 6. Each of these statements addressed: (i) the sufficiency of data supporting Endo's Citizen Petition (¶ 168) and abuse-deterrent labeling submissions (¶¶ 171, 204, 206, 210-11, 219, 241-42, 250); (ii) Defendants' "multi-year ongoing dialogue," collaboration, and meetings with the FDA regarding its data supporting a potential abuse-deterrent label (¶¶ 225-26, 231-32, 250); or (iii) the impact of the FDA Advisory Committee vote to remove Reformulated Opana ER from the market (¶¶ 257, 261-62). None of these statements qualifies for safe harbor protection.

First, Defendants' statements touting the sufficiency of data supporting Endo's Citizen Petition and subsequent efforts to obtain abuse-deterrent labeling rest on the false *factual* premise that then-existing data from post-marketing studies supported their claims, and would result in

positive labeling action from the FDA. As such, each of these statements contained representations of current or historical facts that are *not* protected under the PSLRA safe harbor, even to the extent they were prefaced with "words of futurity or belief." *In re Urban Outfitters, Inc. Sec. Litig*., 103 F. Supp. 3d 635, 649-50 (E.D. Pa. 2015) ("characterizations of past events or current conditions" do not qualify statements for safe harbor protection); *see also PTC Therapeutics*, 2017 WL 3705801, at *15 (same); *Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 478 (S.D.N.Y. 2010) (statements that "incorporate forward-looking aspects into statements of present fact" are ineligible for safe harbor); *AES Corp. v. Dow Chem. Co*., 2001 WL 34367296, at *4 (D. Del. Jan. 19, 2001) ("safe harbor" did not apply to statements of present fact).

Each of these statements is also ineligible for safe harbor protection because each omitted that *then-present* post-marketing surveillance data showed increased IV abuse of Reformulated Opana ER and potentially fatal incidents of TMA/TTP associated with such abuse. *See Viropharma*, 21 F. Supp. 3d at 471 ("omissions of existing facts or circumstances are not forward-looking") (collecting cases).

Moreover, courts have repeatedly concluded that similar misrepresentations are ***not*** forward-looking. *See, e.g.*, *Viropharma*, 21 F. Supp. 2d at 471 (statements regarding the likelihood and timing of FDA approval, and management's belief such approval would occur, were not forward-looking where such statements omitted that FDA previously noted limitations of the data upon which company relied); *see also PTC Therapeutics*, 2017 WL 3705801, at *14 (safe harbor did not apply where company made "affirmative false statements about a drug's efficacy and safety to lull investors into thinking that the clinical data was sufficient to meet FDA efficacy standards").

Second, to the extent any of Defendants' misstatements can be considered forward-looking, none was accompanied by adequate cautionary language. To be sufficient, "[c]autionary language

must be extensive yet specific and touch upon the subject matter of the alleged misrepresentation in order for the safe harbor to apply." *In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *7 (D.N.J. Dec. 15, 2015) (citing *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000) ("a vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks" is inadequate; "to suffice, the cautionary statements must be substantive and tailored to the specific [statement or issue] which the plaintiffs challenge")).

Here, Defendants' general disclosures that: (i) the pharmaceutical industry is "heavily regulated, which creates uncertainty about [Endo's] ability to bring new products to market"; (ii) "the submission of an NDA or ANDA to the FDA . . . does not guarantee that the FDA will grant approval to market the product"; and (iii) "[w]e cannot assure you that the FDA or other regulatory agencies will approve or clear for marketing any products developed by us" (*see* MTD, Ex. 6), are blanket warnings that do not satisfy the safe harbor requirements. *See, e.g.*, *Enzymotec*, 2015 WL 8784065, at *10-11 (disclosure that company is subject to government regulations applies to any company in any industry and is not adequate cautionary language).[11]

If anything, these and other warnings concerning uncertainties in the timing and adequacy of Endo's clinical trials address the risks in bringing a drug to market—not the specific facts concealed from investors during the Class Period regarding Reformulated Opana ER's susceptibility to multiple forms of abuse, the increased rates of IV abuse or the unique health risks like TMA/TTP associated with IV injection of Reformulated Opana ER, as seen in post-marketing

[11] *See also Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1123 (C.D. Cal. 2005) (cautionary language that "[t]he FDA approval process is typically lengthy and expensive, and approval is never certain" could apply to "literally any issuer subject to FDA regulation"); *Irvine v. ImClone Sys., Inc.*, 2003 WL 21297285, at *1 (S.D.N.Y. June 4, 2003) (warnings that company is "subject to [FDA] regulation," and that there are "risks and uncertainties associated with completing pre-clinical and clinical trials . . . [and in] obtaining and maintaining regulatory approval," do not trigger safe harbor protection); *In re Amylin Pharm., Inc. Sec. Litig.*, 2002 WL 31520051, at *9 (S.D. Cal. Oct. 10 2002) ("merely warning investors that FDA may not approve the drug . . . does not warn investors about" specific shortcomings of the trials).

surveillance and other data. Indeed, none of the boilerplate warnings to which Defendants point (MTD, Ex. 6) even mentioned Reformulated Opana ER, much less disclosed these specific risks.[12] Rather, Endo's boilerplate cautionary language could have applied to any drug manufactured by any pharmaceutical company, which is plainly insufficient. *See, e.g.*, *Semerenko*, 223 F.3d at 182; *Sgalambo*, 739 F. Supp. 2d at 478 (disclaimer of general factors that might cause actual results to differ "provide[] no company-specific information, fail[] to link any specific projections to specific risks, and remain[] constant throughout the Class Period" and do not trigger safe harbor protection). Vague warnings such as these are also insufficient where they allude to risks as a potentiality when such risks already exist. *See In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998) ("Warnings of possible adverse events are insufficient to make omissions of present knowledge of certain *future* events legally immaterial.").

Third, each statement that Defendants suggest is protected by the PSLRA safe harbor was made with Defendants' knowledge of the omitted data, which showed increased IV abuse of Reformulated Opana ER and life-threatening events of TMA/TPP associated therewith. As discussed in Section IV.C.1, *infra*, prior to and during the Class Period, Defendants received data showing increased IV abuse with Reformulated Opana ER, yet concealed these adverse facts from investors while touting purported declines in "abuse rates" reflected in the same data. *See In re Cendant Corp. Litig.*, 60 F. Supp. 2d 354, 376 (D.N.J. 1999) (because plaintiff alleged defendant knew statement was false at the time it was made, safe harbor did not apply).

[12] In fact, only in May 2017—***after*** the FDA's Advisory Committee concluded that the risks of the drug outweighed its benefits—did Endo change its putative cautionary language to specifically mention Reformulated Opana ER. *See* MTD, Ex. 6. Even with this belated alteration, Endo's putative cautionary language remained insufficient because Defendants continued to downplay the significance of the Advisory Committee vote—noting that "a number of the Committee members expressed their preference that [Reformulated Opana ER] remain on the market" and declared that it was "business as usual on Opana." ¶¶ 257-58, 261-62.

B. The Alleged Misstatements Are Not Immaterial Opinions or Puffery

Defendants do not dispute that the subject matter of the alleged misstatements is material.[13] Instead, they seek to re-cast their factual and objectively verifiable misrepresentations and omissions as puffery or opinions that are immaterial as a matter of law. These efforts fail.

1. None of the Alleged Misstatements Are Puffery

"If a statement is material, then it cannot be puffing." *Voit v. Wonderware Corp.*, 977 F. Supp. 363, 370 (E.D. Pa. 1997).[14] Further, only general, non-specific optimism is inactionable. *See DFC Global*, 2015 WL 3755218, at *13. ("Far from being a vague statement of intention or optimism, fraudulent comments regarding [] a fundamental aspect of [defendant's] business are of vital importance to investors."). Defendants challenge certain statements as immaterial puffery. MTD, Ex. 5. In attempting to support their flawed arguments, Defendants emphasize portions of the alleged misstatements that are *not* the subject of Plaintiff's falsity allegations. Defendants' efforts to rewrite the Complaint miss the mark.

First, to distract the Court from the statements Plaintiff actually challenges, Defendants selectively emphasize words like "dramatic," "substantial[]," "significant," and "very sharp" that are merely ancillary to the actual content of Defendants' statements touting declines in

[13] The safety and prospects of Reformulated Opana ER, which generated hundreds of millions of dollars in annual revenues, is material to investors. *See Lucent Techs.*, 217 F. Supp. 2d at 559 ("a reasonable investor likely would consider material any information relating to customer acceptance of key products"). Moreover, once Defendants touted Reformulated Opana ER's purported abuse-deterrent properties, and declines in "abuse rates," they had a duty to disclose the data showing that it did not deter abuse, was susceptible to abuse by grinding, cutting, chewing, and injection, and was increasingly abused intravenously from the time it entered the market. *In re Merck & Co., Inc., Sec., Derivative & "ERISA" Litig.*, 2012 WL 3779309, at *3 (D.N.J. Aug. 29, 2012) (when company "put[s] the issue in play," it acquires a duty to disclose all relevant information relating to that issue).

[14] A misrepresentation or omission is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision. *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). "[T]he delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts are peculiarly for the trier of fact." *EP MedSystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 875 (3d Cir. 2000). "*Only if* the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Shapiro*, 964 F.2d at 280 n.11.

Reformulated Opana ER "abuse rates" purportedly reflected in post-marketing data. *Id*. Plaintiff does not allege that Defendants' choice of adjectives describing the purported reductions in Reformulated Opana ER abuse rendered such statements misleading. Rather, Plaintiff alleges that the objectively verifiable *factual claim of a reduction* of abuse rates—whether characterized as "dramatic," "substantial[]," "very sharp" or other—was in and of itself materially misleading because Defendants concealed that the very data upon which they relied in making such statements actually showed an *increase in IV abuse* of the drug. Ex. A § 1; ¶¶ 157, 161, 168, 174, 179, 186, 190, 198.

Second, Defendants incorrectly argue that their statements touting the "sufficiency" and "robust" nature of Endo's post-marketing surveillance data, as support for its Citizen Petition and abuse-deterrent label applications, are immaterial puffery. MTD at 23-24; *id*., Ex. 5. However, a "statement's somewhat effusive language is insufficient to put the statement into the category of puffery" where it is otherwise material. *In re Bristol-Myers Squibb Sec. Litig*., 2005 WL 2007004, at *24 (D.N.J. Aug. 17, 2005) (statement that clinical trial results were "the most compelling we've seen" was "not puffery because it refer[red] specifically to the results from the [] trials—a matter of historical fact"); *see also Freudenberg,* 712 F. Supp. 2d at 191 (statements that "we enter 2007 ideally positioned to capitalize on secular growth trends in the industry" not puffery because they represented current condition and contradicted then existing internal distress); *In re Xerox Corp. Sec. Litig*., 165 F. Supp. 2d 208, 218 (D. Conn. 2001) (allegations "go beyond claims of mere puffery" where "defendants made specific statements, including . . . those characterized by the defendants as merely reflecting optimism, knowing they were contrary to the company's actual situation").

Third, statements, like those at issue here, that "specifically draw a link" between a company's future success and the alleged misrepresented or omitted facts, are not immaterial puffery. *Hurwitz v. LRR Energy, L.P.*, 241 F. Supp. 3d 491, 504 (D. Del. 2017). Specifically, Defendants linked Reformulated Opana ER's abuse-deterrent labeling prospects with the ongoing study data to which Defendants had access by indicating that such data: (i) was sufficiently robust to demonstrate that original Opana ER was withdrawn for safety reasons; (ii) supported their claims concerning the abuse-deterrent properties of the drug; and (iii) would enable Endo to resubmit an abuse-deterrent label for Reformulated Opana ER for FDA approval. Any effusive language describing the objectively verifiable facts in these statements does not transform these material misstatements into immaterial puffery. *See id*. Defendants' statements are also not immaterial puffery because they concerned a "fundamental aspect of [Endo]'s business [] of vital importance to investors." *DFC Global*, 2015 WL 3755218, at *13 (statements about conservative nature of company's underwriting and responsible lending practices were not puffery).

2. To the Extent Any of Defendants' Misstatements Can Be Considered Opinions, They Are Actionable Under *Omnicare*

Opinion statements are actionable where a plaintiff adequately alleges that the statement is objectively false or the speaker disbelieved the stated opinion. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015) (whether an opinion statement is misleading "depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective").[15] Defendants challenge certain of the alleged misstatements

[15] Citing *Amarin*, 689 F. App'x at 132 n.12, Defendants falsely state that "the Third Circuit has declined to extend *Omnicare* to Exchange Act claims." MTD at 22 n.15. In truth, the panel simply "decline[d] to decide whether *Omnicare* is applicable to § 10(b) claims." *Id*. In *Omnicare*, however, the Supreme Court noted that the principles underlying its ruling "are not unique to § 11." 135 S. Ct. at 1330. Thus, *Omnicare* applies equally to Plaintiff's Section 10(b) claims. *See In re Merck & Co.,Inc. Sec., Derivative & "ERISA" Litig.,* 2015 WL 2250472, at *20-21 (D.N.J. May 13, 2015) (finding *Omnicare* instructive in analyzing the viability of plaintiff's alleged misleading opinion statements under Section 10(b)). In any event, Third Circuit law is consistent with *Omnicare* in that opinions

as purportedly inactionable opinions, asserting that they are: (i) "subjective interpretations of data" that are not actionable as a matter of law; or (ii) general expressions of belief that Plaintiff does not adequately allege were not honestly held (subjectively false), or lacked a reasonable basis (objectively false). MTD at 22-23; *id*., Ex. 4. Defendants are wrong.

a. Defendants' Mischaracterize the Misstatements Concerning Abuse Rates as Subjective Interpretations of Data

The alleged misstatements that Defendants challenge as subjective interpretations of data broadly assert that post-marketing data showed declines in "abuse rates" and "rates of abuse" generally, or in the "percentage of abuse . . . by nasal insufflation or snorting." *See* MTD, Ex. 4 (citing ¶¶ 157, 161, 168, 170, 179, 181, 183, 190, 198, 200). Defendants' statements themselves, which refer to specific mathematically calculated percentages (*see, e.g.*, ¶¶ 161, 168, 170, 179, 183, 190, 200), lay bare Defendants' argument that they offered only "subjective interpretations" in their statements. Moreover, Plaintiff alleges that these broad statements were materially misleading because Defendants failed to disclose that *the very same data showed increases* in the rates of IV abuse for Reformulated Opana ER. ¶¶ 111, 123-24, 126, 130-32. It is this material *omission* of data bearing directly upon Defendants' representations concerning abuse rates, rather than the data that Defendants actually discussed, that rendered their statements misleading. *See Omnicare*, 135 S. Ct. at 1332 (when pleading omissions, plaintiff must allege "facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context"). Defendants' interpretation of data concerning abuse rates generally, or intranasal abuse rates in particular (to the extent it is even valid, *see infra* Section IV.C.1) is irrelevant.

---

are actionable if they are not honestly believed or lack a reasonable basis. *See, e.g.*, *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig*., 543 F.3d 150, 166 (3d Cir. 2008).

Similarly, Defendants' statements that Reformulated Opana ER was having the "intended effect on abuse rates and routes of administration" (¶¶ 181-82) were materially misleading, not because Plaintiff disagrees that the data showed a decrease in certain rates or methods of abuse, but rather because the very properties that purportedly deterred certain methods of abuse were simultaneously driving *increased* rates of IV abuse, which Defendants concealed. *See Omnicare*, 135 S. Ct. at 1325 (distinguishing between fact, which is "a thing done or existing" and opinion, which is "a belief[,] a view, or a sentiment which the mind forms of persons or things").[16] Defendants' statements that "development efforts have gone well in terms of the insufflation study," whose results were "positive" and supported Defendants' hypothesis of Reformulated Opana ER's abuse-deterrent potential (¶¶ 183, 219, 227, 237) are likewise misleading because they omitted that data from Endo's post-marketing surveillance of the drug showed increased IV abuse. *Id*.[17]

b. Defendants' Other Purported Opinions Either Contain Embedded Factual Representations or Express Opinions that Defendants Did Not Genuinely Hold

Other statements that Defendants incorrectly characterize as opinions are, nevertheless, actionable because they contained embedded factual representations or Defendants did not honestly hold the purported opinion expressed. *See Omnicare*, 135 S. Ct. at 1329; *In re Valeant Pharm. Int'l, Inc. Sec. Litig*., 2017 WL 1658822, at *14 (D.N.J. Apr. 28, 2017) (omission of facts about the inquiry the issuer did or did not conduct, or the knowledge it did or did not have, which made the statements at issue misleading, was actionable). For example, Defendants argue that

[16] Moreover, these statements are false because dramatically increasing IV abuse clearly was not an intended effect of Reformulated Opana ER.

[17] For these reasons, Defendants' reliance on *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014), for its holding that "[i]nterpretations of clinical trial data are considered opinions" (MTD at 22), is misplaced.

their statements comparing Reformulated Opana ER to reformulated OxyContin, and touting the "sufficien[cy]" and "robust[ness] of post-marketing surveillance data are merely "general expression[s] of belief." MTD, Exs. 4, 5. Defendants are wrong.

As an initial matter, Defendants' representations that the post-marketing data for Reformulated Opana ER was "very strong," "very encouraging," "robust," and "compelling" (¶¶ 172-73, 179, 198) are inextricably linked to the accompanying factual representations that the data showed "lower rates of abuse" and, thus, concern underlying factual representations which are actionable for the reasons set forth above in Section IV.A.1. *See Omnicare*, 135 S. Ct. at 1327 (opinions containing embedded statements of fact were actionable). Further, Defendants' statements that "epidemiological surveillance data that we're getting in is very supportive of what we expect these abuse-deterrent formulations should do i[n] supporting our original contention in this regard" (¶ 171), and touting the purported "sufficien[cy]" of evidence supporting Endo's Citizen Petition and a "determination that the [original Opana ER] was discontinued for reasons of safety" (¶¶ 158, 163, 166, 168, 177, 191) are premised on the underlying factual representation that the data actually demonstrated Reformulated Opana ER's ability to deter abuse. *See id*. In fact, as set forth herein, Defendants knew, Reformulated Opana ER was abused intravenously at escalating rates from the time it entered the market, causing fatal incidents of TMA/TTP unique to the drug.

Defendants' statements concerning the sufficiency of Endo's data in support of an abuse-deterrent label for Reformulated Opana ER (¶¶ 204, 206, 226-27, 232, 237, 241, 246), likewise rest on the premise that the data actually supported such a submission. However, as demonstrated herein, Endo's data for Reformulated Opana ER not only failed to demonstrate the safety of the drug and its ability to deter abuse, but also showed that the increasing rate of IV abuse presented

dangers, including TMA/TTP, that were absent from the original formulation. Moreover, Defendants' knowledge of and reliance upon this data is incompatible with any opinion that the same data supported abuse-deterrent labeling. *See Omnicare*, 135 S. Ct. at 1328-29.

Defendants' assertion that their statements comparing Reformulated Opana ER to the "virtually identical" reformulated OxyContin are subjective interpretations of data (MTD, Ex. 4) similarly fails. These statements are also predicated upon an embedded factual representation that the data, in fact, showed that the two drugs were equally effective at deterring abuse. At the times of these statements, however, Defendants relied upon or had access to contemporaneous data demonstrating that: (i) unlike reformulated OxyContin, which showed "resistance to aqueous extraction" by forming a "viscous hydrogel" when subjected to an aqueous environment, Reformulated Opana ER "can be readily prepared for injection"; (ii) Reformulated Opana ER was abused intravenously from the time it entered the market; and (iii) IV abuse of Reformulated Opana ER was associated with potentially fatal incidents of TMA/TTP unique to the drug. ¶¶ 86, 111. Moreover, even after the FDA rejected Defendants' claims that the drugs were "virtually identical" in denying Endo's Citizen Petition (¶¶ 110, 112), Defendants continued to tout the similarities of these drugs. ¶¶ 219, 237. These facts also undermine any notion that Defendants subjectively believed that these purported opinions were true. MTD, Ex. 4 (citing ¶¶ 185-87, 195, 237).

Courts have held statements to be actionable under similar circumstances. *See, e.g., In re Vivendi,, S.A. Sec. Litig.*, 838 F.3d 223, 246 (2d Cir. 2016) (statements that company had a "very strong balance sheet" contained embedded facts regarding such results); *In re BioScrip, Inc. Sec. Litig.*, 95 F. Supp. 3d 711, 729-30 (S.D.N.Y. 2015) (no subjective belief in company's legal compliance where company was in receipt of civil investigative demand).

C. Plaintiff Pleads the Requisite Strong Inference of Scienter

To plead scienter under Section 10(b) and Rule 10b-5, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Tellabs, Inc. v. Makor Issues & Rights, Ltd*, 551 U.S. 308, 314 (2007). "Allegations giving rise to a strong inference of scienter include . . . facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Urban Outfitters*, 103 F. Supp. 3d at 652.[18] Recklessness is defined as an "extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 267 n.42.

Under *Tellabs*, "while constantly assuming the plaintiff's allegations to be true," a court must consider plausible opposing inferences, if any, in determining whether the pleaded facts give rise to the required "strong" inference of scienter. 551 U.S. at 323, 326-27. An inference of scienter is strong "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id*. at 324. When evaluating a complaint's scienter allegations, a court must consider "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id*. at 323 (emphasis in original). The requisite inference of scienter need not be the "most plausible of compelling inferences," nor does it need to be "irrefutable, i.e., of the 'smoking gun' genre." *Id*. at 324. At the motion to dismiss stage, "a tie favors the plaintiff." *Lormand v. US Unwired, Inc*., 565 F.3d 228, 254 (5th Cir. 2009).

[18] Plaintiff need not establish motive to show scienter where, as here, Plaintiff has shown conscious misbehavior or recklessness. *See Bristol-Myers Squibb*, 2005 WL 2007004, at *27 ("where a plaintiff can produce adequate evidence of scienter by demonstrating conscious misbehavior or recklessness, the question of 'motive' is irrelevant").

As set forth below, Plaintiff adequately pleads scienter through allegations demonstrating that, throughout the Class Period, the Individual 10(b) Defendants [19] made the statements discussed above while knowing or recklessly disregarding the danger of misleading investors. In particular, the Individual 10(b) Defendants: (i) knew or had access to the omitted data that directly contradicted their statements; (ii) would have known about material facts concerning Reformulated Opana ER because it was critically important to Endo's business and they were Endo's senior executives; (iii) spoke repeatedly about the drug, including in response to analysts' questions on conference calls and are presumed to have known or recklessly disregarded the entirety of the data they discussed; and (iv) perpetrated their fraud for nearly five years. *See generally* ¶¶ 157-263. In turn, Plaintiff's theory of the Individual 10(b) Defendants' multi-year campaign of fraud is at least as cogent and compelling as any non-fraudulent inference.

1. The Individual 10(b) Defendants Knew or Had Access to Facts Contradicting Their Public Statements

"To adequately plead scienter, it is sufficient for plaintiffs to allege that defendants had knowledge of facts or access to information that contradict[ed] their statements." *In re Cambrex Corp. Sec. Litig.*, 2005 WL 2840336, at *11 (D.N.J. Oct. 27, 2005); *see also Palladin Partners v. Gaon*, 2006 WL 2460650, at *11 (D.N.J. Aug. 22, 2006) (same).

Here, the Individual 10(b) Defendants knew or had access to information showing that almost immediately after Reformulated Opana ER was introduced to the market: (i) it was

[19] The Individual 10(b) Defendants are Paul Campanelli, Blaine Davis, Matthew Davis, Rajiv Kanishka Liyanaarchchie De Silva, Ivan Gergel, Susan Hall, David P. Holveck, Alan G. Levin, and Julie H. McHugh, collectively. Because each of the Individual 10(b) Defendants was aware of or recklessly disregarded information contrary to Endo's public statements, the scienter of each of these individuals is imputed to the Company. *See Li v. Aeterna Zentaris, Inc.*, 2016 WL 3583821, at *2 (D.N.J. June 30, 2016) (scienter of single senior executive imputed to corporate defendant provided sufficient basis to sustain complaint); *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 597 (D.N.J. 2001) ("scienter sufficiently pled as to a company's agents may be imputed to the company itself").

associated with IV abuse, which continued to increase throughout the Class Period (*see, e.g.*, ¶¶ 88, 98, 111, 123-24, 126, 130-32, 301-04); and (ii) the very properties that Endo claimed made the product safe and less susceptible to abuse were responsible for life-threatening health risks unique to Reformulated Opana ER (*see* ¶¶ 131-32, 304; *supra* Section II). Among other sources, this information was made clear in: (i) post-marketing data from the NAVIPPRO and RADARS databases that Endo regularly received, submitted in support of its Citizen Petition and abuse-deterrent label applications, and publicly relied upon as support for the Individual 10(b) Defendants' false or misleading statements touting purported declines in "abuse rates" for Reformulated Opana ER (¶¶ 87-88, 95, 99, 105); and (ii) the FAERS database, to which the Individual 10(b) Defendants had access (¶¶ 130-31, 301, 304).

These allegations support an inference that the Individual 10(b) Defendants knew or recklessly disregarded that their statements concerning the "crush-resistant" and "abuse-deterrent" properties of Reformulated Opana ER and the purported declines in "abuse rates" observed in post-marketing surveillance data were materially false or misleading. *See Viropharma*, 21 F. Supp. 3d at 473 (scienter adequately pled where defendants' public statements concerning company's main drug were "directly contradict[ed]" by results of company's own study in support of its sNDA); *Campbell Soup*, 145 F. Supp. 2d at 599 (plaintiffs may adequately plead scienter "based on recklessness when they have specifically alleged defendants' . . . access to information contradicting their public statements"); *In re Vicuron Pharma., Inc. Sec. Litig.*, 2005 WL 2989674, at *5-6 (E.D. Pa. July 1, 2005) (scienter adequately alleged where defendants overstated efficacy of lead drug under development while simultaneously concealing unfavorable clinical trial results); *Amylin Pharms., Inc. Sec. Litig.*, 2002 WL 31520051, *7 (scienter adequately alleged where defendant, through studies, "knew that some correlation existed between" diabetes drug and severe

side effect resulting from use, "yet failed to prevent investor confusion with more cautionary language").

In addition, the Individual 10(b) Defendants had access to information from REMS meetings, which were held on a monthly basis to discuss post-marketing data for Reformulated Opana ER. ¶ 297. As set forth herein, this information contradicted the Individual 10(b) Defendants' public statements concerning the putative safety and decreased abuse rates of Reformulated Opana ER, and thus gives rise to a strong inference of scienter. *See PTC Therapeutics*, 2017 WL 3705801, at *16 (scienter adequately pled where "the essential allegation" was that "PTC knew (or recklessly disregarded the obvious risk) that neither the pre-specified data nor the post hoc data, considered alone or collectively, were even facially sufficient").[20]

The Individual 10(b) Defendants argue that certain of them "did not arrive at Endo until several years after these studies" (MTD at 29) and thus could not have had access to the contradictory information Plaintiff alleges. This argument ignores Plaintiff's allegations concerning when the NAVVIPRO, RADARS, and FAERS data was available. Endo and the Individual 10(b) Defendants would like to convince the Court that they only knew or had access to the study data, that they were continually compiling and analyzing from the time Reformulated Opana ER entered the market, *after* Endo submitted its multi-year collection to the FDA in 2016. Yet, as discussed above and alleged in the Complaint, before they submitted this data to the FDA, the Individual 10(b) Defendants not only gathered and analyzed the data but also characterized it

[20] Indeed, the Individual 10(b) Defendants made these representations notwithstanding the FDA's comments: (i) that Endo's data was "inconclusive" as to whether Reformulated Opana ER was abuse-deterrent: and (ii) noting the "troubling" possibility that Reformulated Opana ER was driving increased rates of IV abuse (¶¶ 95, 102, 111). *See Frater*, 996 F. Supp. 2d at 350 ("[w]hen the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity"); *Viropharma*, 21 F. Supp. 3d at 473 (allegation that FDA informed defendants study data was "inadequate" supported strong inference of scienter).

to investors. *See, e.g.*, ¶ 278 (Campanelli in 2017 speaking about all of Endo's "studies to date"); *see also* ¶¶ 174, 255. Thus, Individual 10(b) Defendants had access to data demonstrating the spiking IV abuse rates, throughout this period.[21] That this multi-year data was also aggregated and delivered to the FDA in mid-2016 does nothing to undermine the Complaint's well-pled allegations that the Individual 10(b) Defendants possessed data earlier in the Class Period that contradicted their consistent claims that the abuse-deterrent properties in Reformulated Opana ER were lowering abuse rates.

Fundamentally misunderstanding Plaintiff's allegations, Defendants also incorrectly argue that the FDA's decision to convene an Advisory Committee to review Reformulated Opana ER's risk/benefit profile (and split vote regarding the same) shows that reasonable minds could differ as to the meaning of the safety data for the drug, which negates an inference of scienter. MTD at 28.[22] Plaintiff does not allege a disagreement over scientific data, but rather that the Individual 10(b) Defendants deliberately or recklessly failed to inform the market of the mathematical fact that the rate of IV abuse ***increased*** with Reformulated Opana ER. *PTC Therapeutics*, 2017 WL 3705801, at *14 n.19 (scienter adequately alleged where defendants misrepresented that the "totality of clinical data . . . provide substantial evidence of the effectiveness" of drug but failed to tell investors that the same data contained information that undermined drug's prospects of meeting FDA efficacy standard). As set forth herein, the data unquestionably showed an increase in dangerous IV abuse of Reformulated Opana ER that Defendants repeatedly concealed from

[21] Defendants' argument that "Plaintiff has not pled facts establishing that *any* of the studies or post-marketing data concerning Opana ER contradicted any statement by any defendant at the time" (MTD at 28 (emphasis in original)) is simply incorrect.

[22] Defendants' reliance on *In re Columbia Laboratories Securities Litigation,* 602 F. App'x 80, 84 (3d Cir. 2015), which is non-precedential and easily distinguishable, is misplaced. MTD at 28. There, the FDA's decision to convene an Advisory Panel was only one of four factors that the court concluded, taken together, supported a non-fraudulent inference. Considered holistically with Plaintiff's other scienter allegations, the FDA's decision to convene an Advisory Committee here does not overcome the strong inference of scienter.

investors while simultaneously touting purported declines in "abuse rates" of the drug. Whether researchers could plausibly interpret the data as also showing declines in other forms of abuse is irrelevant to whether Defendants intentionally or recklessly omitted the undisputed increase in IV abuse unique to Reformulated Opana ER from their public statements promoting the drug's putative success at deterring abuse.

2. The Individual 10(b) Defendants' Senior Positions, Along with Reformulated Opana ER's Status as Endo's Key Product Create a Strong Inference of Scienter

It is well settled that "knowledge may be imputed to individual defendants when the disclosures involve the company's core business," *Campbell Soup.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001), "when taken together with additional allegations connecting the executives' positions to their knowledge." *Urban Outfitters*, 103 F. Supp. 3d at 654 (quoting *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246-47 (3d Cir. 2013)). Moreover, "a person's status as a corporate officer, when considered alongside other allegations, can help support an inference that this person is familiar with company's most important operations." *PTC Therapeutics*, 2017 WL 3705801, at *17 (brackets omitted).

Here, the Complaint details how original and Reformulated Opana ER were central to Endo's success and, thus, represented a "core operation" of the Company about which the Individual 10(b) Defendants were no doubt aware. *See* ¶¶ 306-09. Endo earned hundreds of millions of dollars annually from selling Reformulated Opana ER during the Class Period (¶ 56), and disclosed in Class Period SEC filings that "***most*** of [its] total revenues come from a small number of products," one of which was Opana ER (¶ 306). Endo also touted Reformulated Opana ER as a "significant" part of its U.S.-branded pharmaceutical business (¶ 308). *See Vicuron*, 2005 WL 2989674, at *7 (where drug was the "lead product in development [] its importance to the company supports at least a strong inference of recklessness of ***all the company's officers***"); *In re*

Viropharma, Inc. Sec. Litig., 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) (imputing knowledge under core operations theory where drug company's "highest ranking members," alleged to have misstated information about its leading drug product, undisputedly had access to clinical trial reports questioning the efficacy and safety of that drug).

Reformulated Opana ER also significantly impacted Endo's business because the Company depended upon sales of the drug to fund, among other things, research and development projects throughout the Company. ¶ 309; *Viropharma*, 21 F. Supp. 3d at 473 (core operations supported strong inference of scienter where drug significantly impacted "revenue and profit margins"); *Avaya*, 564 F.3d at 271 ("The perceived importance of margins supports an inference that McGuire, Avaya's Chief Financial Officer, was paying close attention to these numbers"); *see also Mill Bridge V, Inc. v. Benton*, 2009 WL 4639641, at *31 (E.D. Pa. Dec. 3, 2009) ("where the [omitted or misrepresented] information relates to the organization's core business, such facts are powerful circumstantial evidence of scienter"). Indeed, Opana ER's importance to Endo led the Company to deploy considerable resources to foreclose competition from generics. ¶¶ 57-65, 80-94.

Moreover, IV abuse data was particularly important to Endo because the FDA specifically identified the potential for intravenous abuse as "troubling" (¶ 111) and further noted that the drug could "be readily prepared for injection" (¶ 107). Consequently, the Individual 10(b) Defendants had every reason to know of the adverse IV abuse data concerning this core product. Nevertheless, fully aware of the importance of this data, the Individual 10(b) Defendants deliberately concealed it from investors.

These allegations, coupled with the Individual 10(b) Defendants' senior positions at the Company—including, for example, CEO, CFO, President, and Director—further support an

inference that they either intentionally or recklessly concealed: (i) the increase in IV abuse with Reformulated Opana ER; (ii) the serious health hazards associated with such abuse; and (iii) the grim commercial prospects resulting from such abuse. *See, e.g.*, *Avaya*, 564 F.3d at 269-70 (defendant positions as "corporate officer" one factor considered in scienter analysis); *Viropharma*, 2003 WL 1824914, at *9 ("because of the Defendants' positions in the company they had access to several documents which contained the facts that allegedly made the Defendants' statements materially misleading"); *Feinberg v. Benton*, 2007 WL 4355408, at *6 (E.D. Pa. Dec. 3, 2007) ("a court may factor in the position of the defendant as circumstantial evidence when the information is of great importance to the company"). The scienter of the Individual 10(b) Defendants is sufficient to establish Endo's corporate scienter. *See supra* note 19.

3. The Individual 10(b) Defendants' Consistent and Repeated Misstatements Regarding Reformulated Opana ER Strengthen the Scienter Inference

Further bolstering the inference that the Individual 10(b) Defendants knew or recklessly disregarded adverse data and information concerning the safety and abuse-deterrent properties of Reformulated Opana ER is the indisputable fact that these Defendants repeatedly addressed the following issues (among others) in their public statements: (i) the purported safety of the drug (¶¶ 67-69, 71-73, 88, 99, 123-26); (ii) abuse rates of the drug (¶¶ 157, 159, 181-82); and (iii) the prospects of securing abuse-deterrent labeling for the drug based on post-marketing data (¶¶ 128, 204, 206, 210-11, 219, 225-27, 231-33, 241-42, 250); *supra* Section II.

The Individual 10(b) Defendants' repeated statements regarding this core aspect of Endo's business, considered together with the other facts alleged in the Complaint, support a strong inference of scienter. *See, e.g.*, *PTC Therapeutics*, 2017 WL 3705801, at *16 (finding "powerful evidence of scienter" where defendants spoke "explicitly and repeatedly" about studies of company's most important drug); *Enzymotec*, 2015 WL 8784065, at *18 ("the matter at issue is

central to the core business of the Company, about which Defendants spoke regularly"); *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 810 (C.D. Cal. 2011) (scienter adequately alleged where "[d]efendants made a series of statements" describing the FDA's "'vetting' of, 'approval' of, and 'agreement' with their bioequivalency studies" yet FDA denied approval because studies were inadequate).[23]

Further evidencing the Individual 10(b) Defendants' scienter are their detailed responses to specific questions from analysts concerning Reformulated Opana ER. *See, e.g.*, ¶¶ 158, 171, 174, 232, 246, 262; *Avaya*, 564 F.3d at 269-70 ("It is one thing for a plaintiff to claim that a defendant must have known its earnings projections were false because of the existence of unusual price reductions. . . . But it is another thing when a defendant chief financial officer is ***specifically asked, directly and repeatedly***, whether the company's pricing has held steady despite the competitiveness of the market."); *S. Ferry LP #2 v. Killinger*, 687 F. Supp. 2d 1248, 1259-60 (W.D. Wash. 2009) (fact that CEO answered analysts with "high degree of specificity" supports a finding of scienter). Similarly, analysts' focus upon Reformulated Opana ER during the Class Period (*see, e.g.*, ¶¶ 171-72, 174, 197-98, 206, 211, 226-27, 232, 237, 242, 246, 261-62), further supports scienter. *See, e.g.*, *Avaya*, 564 F.3d at 270 ("specificity and repetition of the analysts' questions" supported strong inference of scienter); *Fresno Cnty. Emps.' Ret. Assoc. v. comScore, Inc.*, 268 F. Supp. 3d 526, 553 (S.D.N.Y. 2017) ("The fact that revenues and other related metrics were key to measuring [comScore's] financial performance and [were] a subject about which investors and analysts often inquired further reinforces the inference of scienter."); *Urban Outfitters*, 103 F. Supp. 3d at 653 ("In the context of specific inquiries about pricing and sales

[23] While repeated misstatements strengthen an inference of scienter, a securities fraud action may proceed into discovery based on a single misstatement. *See, e.g.*, *SEC v. Farmer*, 2015 WL 5838867, at *7 n.8 (S.D. Tex. 2015) ("even a single misstatement or omission is sufficient for liability"); *SEC v. Morgan Keegan & Co., Inc.*, 678 F.3d 1233, 1248 (11th Cir. 2012) (same).

trends, and the consistent content of [the CEO] and [the CFO's] responses, defendants' omission of actual circumstances that were contrary to their answers presents 'an obvious risk of misleading investors.'" (quoting *Avaya*, 564 F.3d at 270 n.43)).

4. The Duration of the Individual 10(b) Defendants' Fraud Bolsters Scienter

The duration of the Individual 10(b) Defendants' alleged fraud also supports a strong inference of scienter. ¶¶ 157-263; *see, e.g.*, *In re Rent-Way Sec. Litig.*, 209 F. Supp. 2d 493, 507 (W.D. Pa. 2002) (alleged fraud spanning several years supported strong inference of scienter); *In re Genworth Fin. Inc. Sec. Litig.*, 103 F. Supp. 3d 759, 785 (E.D. Va. 2015) ("that Defendants made repeated misrepresentations over the course of a year also suggests a substantial degree of scienter"); *In re Pall Corp.*, 2009 WL 3111777, at *8 (E.D.N.Y. Sept. 21, 2009) (duration of fraud one factor supporting scienter); *see also Enzymotec*, 2015 WL 8784065, at *18 (defendants' statements addressing drug "regularly" for nearly a year supported strong inference of scienter). Here, the Individual 10(b) Defendants delivered a consistently false or misleading message to investors over the course of the nearly five-year Class Period, that: (i) data they were gathering and reviewing confirmed Reformulated Opana ER's safety and abuse-deterrence (¶¶ 67-69, 71-73, 88, 99, 123-26); (ii) this data reflected declines in abuse rates when in fact, it showed increased IV abuse (*see, e.g.*, ¶¶ 157, 159, 161, 170-72, 181-82); and (iii) given these results, the Company was in a favorable position to secure abuse-deterrent labeling for the drug (¶¶ 128, 204, 206, 210-11, 219, 225, 227, 231-33, 241-42, 250). This multi-year campaign of misinformation further supports a finding of scienter. *See Rent-Way*, 209 F. Supp. 2d at 507.

5. Plaintiff's Allegations of Fraud are at Least as Compelling as the Individual 10(b) Defendants' Non-Fraudulent Counternarrative

Plaintiff alleges that the Individual 10(b) Defendants deployed Company resources in numerous efforts to insulate Endo's Opana ER franchise from generic competition, seeking to

protect the critical revenues that Endo derived from the product. In connection with these measures, the Individual 10(b) Defendants failed to disclose adverse facts concerning IV abuse of Reformulated Opana ER and the unique and serious accompanying health risks. Although the Individual 10(b) Defendants may have believed that they could successfully obscure study data demonstrating a spike in IV abuse of Reformulated Opana ER, even after the FDA viewed the evidence as "troubling" in 2013, the Individual 10(b) Defendants pressed forward. They coupled their advocacy before the FDA with a public campaign directed to investors, which also was predicated on obfuscating the true facts. ¶ 43.

Defendants' lies to the FDA, investors, and the public at large about the tremendous health risks presented by Reformulated Opana ER, which have also given rise to a Department of Justice criminal investigation (¶ 45) bolsters the already strong inference of scienter. *See, e.g.*, *In re ITT Educ. Servs. Inc. Sec. Litig.*, 34 F. Supp. 3d 298, 309 (S.D.N.Y. 2014) ("pending investigations" are properly considered "as evidence of scienter."); *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 380 (E.D.N.Y. 2013) ("[C]ourts have considered a governmental investigation as one piece of the puzzle when taking a 'holistic' view of the purported facts as they relate to scienter."). Likewise, Endo's conduct contributed to the formation of a coalition of forty-one State Attorneys General to investigate opioid manufacturers' marketing practices, of which, at least six have initiated civil lawsuits. *See, e.g.*, *State of Ohio ex rel. Mike DeWine, Ohio Attorney General v. Purdue Pharma L.P.*, No. CV-17 CI 000261 (Ross Cty. Ct. Com. Pl.). Numerous cities and counties, including Philadelphia have also commenced litigation. *See, e.g.*, *City of Philadelphia v. Allergan PLC*, No. 180102718 (Ct. Com. Pl. Phila.).

Without citing any support, Defendants suggest that the far more compelling inference is that "Endo and its executives advocated for Opana ER with the FDA over five years, were

optimistic that they would succeed, and that, in a changing environment with additional data and a new focus on opioid abuse the FDA eventually reached a different conclusion." MTD at 30-31. This self-serving counternarrative, however, cannot be drawn from the face of the Complaint, and ignores the Individual 10(b) Defendants' unwavering omission of known adverse information concerning Reformulated Opana ER during the same time period. *Freshpet*, 2018 WL 394878, at *3 (on a motion to dismiss the court must accept as plaintiff's factual allegations as true).

Viewed in their totality, as *Tellabs* requires, Plaintiff's allegations of Defendants' scienter are at least as cogent and compelling as Defendants' efforts to portray Endo and Reformulated Opana ER as hapless victims of the opioid epidemic in which both were key participants. *See In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 270 (S.D.N.Y. 2010) (rejecting argument that company's problems resulted from unpredictable circumstances because the conduct alleged, "if true, would make [defendants] an active participant in the collapse of their own business").

D. Plaintiff Sufficiently Alleges Control Person Liability

Defendants' sole challenge to Plaintiff's claims for control person liability under Section 20(a) of the Exchange Act and Section 15 of the Securities Act is that Plaintiff has not adequately alleged a primary violation of either Act. MTD at 31. Because Plaintiff has adequately pled claims under Section 10(b) and Section 11, *see supra* Section IV, Defendants have failed to articulate any basis for dismissing Plaintiff's control person claims. *See Hurwitz*, 241 F. Supp. 3d at 505 (sustaining control person claims under Sections 20(a) and 15 where underlying violations were properly plead and defendants did not contest allegations that they were controlling persons).

E. *Colorado River* Does Not Apply to Plaintiff's Securities Act Claims

Defendants seek dismissal of Plaintiff's Securities Act claims under *Colorado River*, which allows a federal court to abstain from exercising jurisdiction when there is an ongoing "parallel" state court proceeding. In effect, Defendants ask this Court to surrender its lawful jurisdiction over

these claims to the Pennsylvania Commonwealth court presiding over *MissPERS* because both cases involve the June 2015 Offering of Endo common stock, despite the fact that they involve different claims, misstatements, allegations, and parties. As Plaintiff's Securities Act claims—and this case as a whole—are not sufficiently similar to *MissPERS*, the Court can swiftly dispose of Defendants' abstention request.[24]

Colorado River abstention "is an ***extraordinary*** and ***narrow*** exception to the duty of a District Court to adjudicate a controversy properly before it." *Id.* at 813; *see also Rarick v. Federated Serv. Ins. Co.*, 852 F.3d 223, 225 (3d Cir. 2017) ("federal courts have a '***virtually unflagging obligation***' to exercise jurisdiction over actions seeking legal relief"). To this end, the Supreme Court has cautioned that the "task in cases such as this is not to find some substantial reason for the *exercise* of federal jurisdiction by the district court; rather, the task is to ascertain whether there exist exceptional circumstances, the clearest of justifications, that can suffice to justify the surrender of that jurisdiction." *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 25 (U.S. 1983) (emphasis original). These exceptional circumstances exist "only when there is a strong federal policy against [] litigation in federal court." *Spring City Corp. v. Am. Bldgs. Co.,* 193 F.3d 165, 172 (3d Cir. 1999); *see also Colo. River*, 424 U.S. at 813 (abdication of jurisdiction must "clearly serve an important countervailing interest").

Courts evaluating whether *Colorado River* abstention is appropriate apply a two-part test: (i) "determine whether the federal and state proceedings are parallel," *Golden Gate Nat'l Sr. Care, LLC v. Minich ex rel. Estate of Shaffer*, 629 F. App'x 348, 350 (3d Cir. 2015); and, if so (ii) apply

[24] There is no requirement that Plaintiff obtain Court approval to bring Securities Act claims on behalf of the Class. *See* MTD at 10 n.6. Lead plaintiffs appointed pursuant to the PSLRA routinely bring claims and allegations in an amended complaint that were not set forth in a different plaintiff's initial pleading. *See, e.g.*, *Thomas v. Magnachip Semiconductor Corp.*, 2015 WL 3749784, at *4 (N.D. Cal. June 15, 2015) (collecting cases) ("In general, republication [of notice under the PSLRA] is not required where a complaint expands the class period or includes an additional defendant or a closely related new claim.").

"a multi-factor test to determine whether extraordinary circumstances meriting abstention are present." *Nationwide, Mut. Fire Ins. Co. v. George V. Hamilton, Inc.*, 571 F.3d 299, 308 (3d Cir. 2009). Under this test, abstention is not warranted here.

1. The Securities Act Claims Are Not "Parallel" to *MissPERS*

"Parallel proceedings are those that are ***truly duplicative***, that is, when the parties and the claims are ***identical***, or at least ***effectively the same***." *Kelly v. Maxum Specialty Ins. Grp.*, 868 F.3d 274, 285 (3d Cir. 2017). Cases are not "parallel" under *Colorado River* where the "federal court case involves claims that are distinct from those at issue in a state court case," including where the parties employ "substantially different approaches [which] might achieve potentially different results." *Id.*; *see also Univ. of Md. at Balt. v. Peat Marwick Main & Co.*, 923 F.2d 265, 276 (3d Cir. 1991) (abstention inappropriate where there is a "lack of identity of all issues" between lawsuits and "no theoretical obstacle to both actions proceeding independently").

Even a cursory review of the pleadings in this case and *MissPERS* reveals that there are significant differences precluding a finding that the Securities Act claims are "parallel." For example, Plaintiff's Section 11 claims here are premised upon untrue or materially misleading statements concerning the "abuse-deterrent" properties of Reformulated Opana ER—a branded pharmaceutical. *MissPERS*, on the other hand, alleges that Endo misled investors by failing to disclose known, adverse trends in sales within Endo's *generic division*, and that division's unsustainable business practice of "trade loading" ("offering deep-pocketed customers excess inventory at the end of the quarter, often at steep discounts, to meet sales goals"). *Compare* ¶¶ 370-73 *with* MTD, Ex. 2 at ¶¶ 1-13, 59-73. The *MissPERS* complaint does not mention Reformulated Opana ER (*see* MTD, Ex. 2), and the Securities Act claims here are not based on any allegations pertaining to Endo's generic division. Consequently, Plaintiff and MissPERS point to different statements made in connection with the June 2015 Offering as the bases for their respective Section

11 claims. *Id*. Moreover, MissPERS asserts Securities Act claims against the underwriters for the June 2015 Offering, while Plaintiff does not. *Compare* ¶¶ 354-65 *with* MTD, Ex. 2 at ¶¶ 19-30, 32-41.

In addition, the claims and parties in the two cases differ, as Plaintiff asserts claims under Sections 10(b) and 20(a) of the Exchange Act that MissPERS does not bring, and against defendants who are not parties to the *MissPERS* action. Further, because common facts underlie Plaintiff's Securities Act and Exchange Act claims, there are no efficiencies gained by litigating the latter at the exclusion of the former in this case—a reality Defendants ignore. This should end the Court's inquiry. *See Yang v. Tsui,* 416 F.3d 199, 204 n.5 (3d Cir. 2005) (state and federal action which involved "distinct determinations" not parallel).[25]

2. Even if The Securities Act Claims Were Parallel to *MissPERS*, There Are No "Extraordinary Circumstances" That Warrant Abstention

Courts consider six factors to determine whether parallel proceedings present "extraordinary circumstances" warranting abstention: "(1) [in an *in rem* case,] which court first assumed jurisdiction over [the] property; (2) the inconvenience of the federal forum; (3) the desirability of avoiding piecemeal litigation; (4) the order in which jurisdiction was obtained; (5) whether federal or state law controls; and (6) whether the state court will adequately protect the interests of the parties." *Nationwide*, 571 F.3d at 308. No one factor is dispositive, and the

[25] *Allied Nut & Bolt, Inc. v. NSS Industries, Inc.* is not to the contrary, as the federal case was found to be parallel to the state case where both actions involved disputes regarding the same contract and the same conduct. 920 F. Supp. 626, 631 (E.D. Pa. 1996). This also is not the type of "claim splitting" Defendants' authorities suggest. *See, e.g.*, *Prewitt v. Walgreens Co.*, 2013 WL 6284166, at *5 (E.D. Pa. Dec. 2, 2013) ("Very often, the doctrine of claim splitting applies to bar a plaintiff from filing a new lawsuit after the court in an earlier action denied leave to amend the complaint to add those claims."). Plaintiff here is not seeking to litigate claims dismissed by another court. More to the point, as noted above, this case and the *MissPERS* case do not involve a "single alleged wrong," *Prewitt*, 2013 WL 6284166, at *5, or the "same subject matter . . . in the same court," *id*. at *5 n.23, *Walton v. Eaton Corp.*, 563 F.2d 66, 70 (3d Cir. 1977), such that claim splitting would even be implicated.

"balancing of factors is heavily weighted in favor of the exercise of jurisdiction." *Id.* These factors overwhelmingly support the Court's exercise of jurisdiction over Plaintiff's Securities Act claims.

First, this is not an *in rem* action. *See In re Bank of Am. Corp. Sec., Derivative & ERISA Litig.*, 757 F. Supp. 2d 260, 345 (S.D.N.Y. 2010) ("The first factor favors the exercise of jurisdiction, because this is not an *in rem* action."). *Second*, Defendants cannot reasonably argue that the federal court in Philadelphia is inconvenient, given that the Company is headquartered in this District. *See Golden Gate*, 629 F. App'x at 351 (no inconvenience where federal court in Philadelphia was 70 miles from Lancaster County state action). Moreover, given this Court's exclusive jurisdiction over Plaintiff's Exchange Act claims, Defendants will be required to defend against these claims in this Court. *Third*, there is no "strongly articulated *congressional policy* against piecemeal litigation in the specific context of th[is] case" alleging securities law claims, and Defendants do not suggest otherwise. *Ryan v. Johnson*, 115 F.3d 193, 198 (3d Cir. 1997) (emphasis in original); *see also Carsten v. Boylan*, 2018 WL 1696649, at *4 (M.D. Pa. Apr. 6, 2018) ("the mere existence of piecemeal litigation is not sufficient to justify abstention"); *cf. Cyan, Inc. v. Beaver Cty. Emps.' Ret. Fund*, 138 S. Ct. 1061, 1063 (2018) (noting "general rule that state and federal courts have concurrent jurisdiction over all claims to enforce the 1933 Act").[26]

Fourth, the fact that the *MissPERS* action was filed approximately six months before this case does not favor abstention. *See Golden Gate*, 629 F. App'x at 351 ("priority should not be measured exclusively by which complaint was filed first . . . the federal court should exercise jurisdiction where . . . no substantial proceedings . . . ha[ve] taken place in state court"). *Fifth,*

[26] Defendants' suggestion that piecemeal litigation would result if Plaintiff's Securities Act claims proceed in this Court ignores completely the fundamental differences in the alleged misstatements underlying the claims in each case. The discovery relevant to proving plaintiff's claims in MissPERS will focus on Endo's generic division, while the discovery in Plaintiff's action before this Court will focus upon entirely different issues, including the safety, attributes, and sustainability of Reformulated Opana ER (as to which Endo's generic division had zero involvement).

federal law—the Securities Act—unquestionably controls here, and "the presence of federal-law issues must always be a major consideration weighing against surrender." *Id.* (citing *Moses H. Cone*, 460 U.S. at 26); *see also Aozora N.Z. LTD. v. Fru-Veg Mktg., Inc.*, 2018 WL 1545585, at *8 (E.D. Pa. Mar. 29, 2018) (refusing to stay case involving federal statute). *Last*, where there is "no indication that the Pennsylvania courts are unable to protect the parties' interests," this factor is neutral. *See Golden Gate*, 629 F. App'x at 352 ("we attribute no weight to this factor").

These factors do not individually—let alone collectively—establish the "extraordinary circumstances" necessary for abstention. Accordingly, even if Plaintiff's Securities Act claims and the *MissPERS* case were "parallel," which they are not, abstention under *Colorado River* is inappropriate.

F. The Complaint Is Not a "Puzzle Pleading"

Defendants also baselessly challenge the Complaint as a "puzzle-pleading" because (to avoid repetition), it internally cross-references paragraphs setting forth the reasons why an alleged misstatement is false, as well as additional facts supporting the reasons for falsity. Defendants' protest that they cannot "match up" the alleged misstatements with the reasons why they are alleged to be false (MTD at 15-17), rings hollow as Defendants plainly had no difficulty understanding Plaintiff's allegations or "matching up" the alleged misstatements with the reasons why each was false or misleading. *See In re Intuitive Surgical Sec. Litig.*, 65 F. Supp. 3d 821, 831 (N.D. Cal. 2014) (complaint was not a puzzle pleading in part because, "[a]s evidenced by Exhibit A to their Motion to Dismiss, Defendants can parse out with relative ease the statements at issue and the reasons as to why they are alleged to be false and misleading").

Moreover, Plaintiff's Complaint here is nothing like the one at issue in *Lord Abbott Affiliated Fund, Inc. v. Navient Corporation*, 2017 WL 3891676, at *3 (D. Del. Sept. 6, 2017). MTD at 15-16. In *Lord Abbott*, the plaintiff: (i) quoted or referenced more than forty SEC filings

and press releases covering multiple aspects of Navient's business without always identifying which portions of the statements were challenged as false or misleading; and (ii) included only a single paragraph alleging that the challenged statements in the preceding fifty paragraphs were false or misleading for any one of several reasons regarding different aspects of the corporate defendant's business. *Id*. Not only are these deficiencies absent from the Complaint, but Plaintiff here specifically alleges, for ***each date that Defendants made a challenged statement***: (i) why each statement was false or misleading; and (ii) the "particular" factual bases supporting each reason why such statement was false or misleading, including where those factual bases are alleged in further detail. *See, e.g.*, ¶¶ 160, 189, 203. This is appropriate internal citation, not a "puzzling" cross-reference.

Further, to avoid repetition, where the reasons why a statement was false or misleading are the same as those applicable to a challenged statement alleged in an earlier paragraph, Plaintiff cross-references earlier paragraph(s) of the Complaint. Where a statement is alleged to be false or misleading for a reason other than or in addition to those set forth in the initially referenced paragraph, Plaintiff sets forth the other or additional reasons why such statement is false or misleading. *See, e.g.*, ¶ 189. Rather than promote confusion, Plaintiff's pleading avoids the unnecessary repetition that Defendants appear to suggest as the preferred alternative approach.

The framework for Plaintiff's allegations has been endorsed in numerous actions under the PSLRA. *See, e.g.*, *City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp*., 2011 WL 2650717, at *7 (W.D. Mich. July 6, 2011) (the "use of a single set of reasons to explain why various statements [a]re false . . . is an acceptable means of identifying the reasons for falsity" and "a permissible way to establish falsity"); *In re Tyco Int'l, Ltd*., 2004 WL 2348315, at *9 (D.N.H. Oct. 14, 2004) ("list[ing] all of the misleading statements in one section but describe[ing] the accounting schemes

that make the statements misleading in different sections" is "a reasonable way to address a complicated securities fraud case [and] does not" render complaint a puzzle-pleading).

Even if the Court determines that any part of the Complaint is difficult to follow, dismissal is not appropriate. Defendants' own authority makes clear that Plaintiff should be granted leave to amend to cure any perceived deficiencies as this contention goes to the form of the pleading, not its merits. *Lord Abbett*, 2017 WL 3891676, at *3 (allowing amendment to cure perceived puzzle pleading deficiencies). Similarly, leave to amend should be granted to the extent the Court finds any of the particularity requirements not satisfied. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1435 (3d Cir. 1997) (allowing amendment "because we are hesitant to preclude the prosecution of a possibly meritorious claim because of defects in the pleadings").

V. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that Defendants' Motion.

Dated: May 4, 2018

Respectfully submitted,

KESSLER TOPAZ
MELTZER & CHECK LLP

s/ Sharan Nirmul
Sharan Nirmul (PA # 90751)
Johnston de F. Whitman, Jr. (PA # 207914)
Michelle M. Newcomer (PA # 200364)
Margaret E. Mazzeo (PA # 312075)
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
snirmul@ktmc.com
jwhitman@ktmc.com
mnewcomer@ktmc.com
mmazzeo@ktmc.com

Counsel for Lead Plaintiff SEB Investment Management AB

CERTIFICATE OF SERVICE

I, Sharan Nirmul, hereby certify that on May 4, 2018, a true and correct copy of the foregoing Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint has been filed electronically with the Clerk of Court, is available for viewing and downloading from the ECF system, and will be served by operation of the Court's ECF system to all counsel of record.

s/ Sharan Nirmul
Sharan Nirmul